

DECLARATION OF CONFORMITY

Manufacturer's Name: M Dialysis AB

Manufacturer's Address: Hammarby Fabriksväg 43
SE-120 30 Stockholm
SWEDEN

SRN: SE-MF-000017466

Product group: Microvials

Intended purpose: Microvials are test-tubes which are used to collect samples from microdialysis catheters, to be analyzed in ISCUS/ISCUS^{flex} Microdialysis Analyzers

Risk class: IVDR, Class A

Basic UDI-DI: 77332699_330_007_X6

Notified Body: N/A

Conformity assessment: Self Declaration

Type designation/model:

Catalogue number (REF)	Product name
P000001	Microvials
P000154	Microvials in rack, Sterile
P000028	Microvial rack

We hereby declare that the above mentioned device(s) comply with applicable requirements in EU *in vitro* diagnostic Medical Device Regulation (IVDR) 2017/746.

This EU Declaration of conformity is issued under the sole responsibility of the manufacturer.

Date and place of issue

2023-08-21
Stockholm

Name, position and signature



Olof Nord, CEO

Document No. D10324-01	Document Name IVDR Declaration of Conformity Microvials
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